



2066985

Accession No. 405399-03

DATA EVALUATION RECORD

1. **CHEMICAL:** Verbenone. Shaughnessey Number: 128986.
2. **TEST MATERIAL:** Verbenone; Lot # B-86; 100% active ingredient; a clear liquid.
3. **STUDY TYPE:** Avian Single-Dose Oral LD50 Test.
Species Tested: Bobwhite quail (Colinus virginianus).
4. **CITATION:** Grimes, J. and M. Jaber. 1988. Verbenone: An Acute Oral Toxicity Study with the Bobwhite. Submitted by Phero Tech Inc., Vancouver, B.C., Canada. Study performed by Wildlife International Ltd., Easton, MD. Laboratory Study No. 209-105. EPA Accession No. 405399-03.
5. **REVIEWED BY:**

Michael L. Whitten, M.S.
Wildlife Toxicologist
KBN Engineering and
Applied Sciences, Inc.

Signature: *Michael L. Whitten*
Date: 8-4-89
6. **APPROVED BY:**

James R. Newman, Ph.D.
Project Manager/
Principal Scientist
KBN Engineering and
Applied Sciences, Inc.

Signature: *James R. Newman*
Date: 8/10/89

Henry T. Craven, M.S.
Supervisor, EEB/HED
USEPA

Signature:
Date:
7. **CONCLUSIONS:** The acute oral LD50 of Verbenone was determined to be greater than 300 mg/kg, the highest dosage tested. The no-observed-effect dosage was 300 mg/kg. The study is scientifically sound and, based on a maximum application rate of 35 grams/acre, meets the requirements for an avian single dose oral LD50 test.
8. **RECOMMENDATIONS:** N/A

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9. **BACKGROUND:**

10. **DISCUSSION OF INDIVIDUAL TESTS:** N/A.

11. **MATERIALS AND METHODS:**

- A. **Test Animals:** The birds used in the study were 21 week old Bobwhite quail (Colinus virginianus), obtained from Fritts Quail Farm, Phillipsburg, NJ. All birds were acclimated to the facilities for 7 weeks prior to initiation of the study. Birds exhibiting abnormal behavior or physical injury during acclimation were not used in the test.
- B. **Test System:** All birds were housed indoors in 78 cm x 51 cm wire pens. Floors were sloped resulting in a ceiling height of 20 to 25 cm. Fluorescent lights provided eight hours of light per day. The temperature averaged approximately 21°C with an average relative humidity of 35%.
- C. **Dosage:** 14-day single dose oral LD50 test. The nominal dosages selected for the study were 39, 65, 108, 180, and 300 milligrams of Verbenone per kilogram of body weight. "The test material was dispersed in corn oil. The concentration of the test material in the diluent was adjusted to provide a constant volume to body weight dosage for all treatment birds. The dosages and LD50 were not corrected for purity of the test substance."
- D. **Design:** Groups of ten birds (five males and five females) were randomly assigned to each of the five treatment groups and the control group. Each dosage group was assigned two pens. One pen contained five males and the other five females. The birds were fed a game bird ration formulated to Wildlife International Ltd.'s specifications. Food and water were supplied ad libitum except for a period of "at least 15 hours" prior to dosing when the birds were fasted. At test initiation, a single dose of test material in diluent (corn oil) was orally intubated into the crop or proventriculus of each bird using a stainless steel catheter. Each bird was individually weighed and dosed on the basis of milligrams of test substance per kilogram of body weight. The control birds received diluent only. All treatment and control birds received a constant dosage volume of 4 milliliters per kilogram of body weight. The birds were individually weighed at test initiation and by group on days 3, 7, and 14.

Group food consumption was recorded on test days 3, 7, and 14. Observations were conducted at least twice daily for potential clinical signs indicative of test material effect.

E. **Statistics:** The mortality pattern was not conducive to calculating the LD50 value. The LD50 was thus estimated to be higher than the highest dosage tested. No statistical analyses of body weight or food consumption were reported.

12. **REPORTED RESULTS:** There were no mortalities in the control group nor in any treatment group. No signs of toxicity were observed in any group. All birds in all groups were normal in appearance and behavior throughout the study.

When compared to controls there was no treatment related effect on body weight or food consumption (Table 2, attached).

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:**

The acute oral LD50 of Verbenone was determined to be greater than 300 mg/kg, the highest dosage tested. The no-observed-effect dosage was 300 mg/kg.

The study was conducted in conformance with Good Laboratory Practice regulations. The data were inspected and the final report signed by the Quality Assurance Manager of Wildlife International Ltd.

14. **REVIEWER'S DISCUSSION AND INTERPRETATION OF STUDY RESULTS:**

A. **Test Procedure:** The test procedures were in accordance with SEP guidelines except for the following deviation:

Body weights were measured by group at the end of the study. According to the SEP, individual body weights should be measured.

B. **Statistical Analysis:** The LD50 was not calculated since no birds died during the study. The LD50 is assumed to be greater than the highest dosage tested (300 mg/kg).

C. **Discussion/Results:** An examination of Table 2 (attached) indicates a marked loss in body weight among females in the 108 mg/kg group during days 7-14. This does not appear to be treatment related.

Since no mortalities or abnormal behavior were observed, the LD50 of Verbenone was determined to be greater than

300 mg/kg, the highest dosage tested. The no-observed-effect dosage was 300 mg/kg.

Subdivision M guidelines require the test to establish that the LD50 is greater than the maximum test dosage. The report states that the maximum application rate of the test chemical is 35 g/acre. In accordance with Subdivision M, the resulting maximum test dosage is 155 mg/kg. The LD50 established in the test thus satisfies this requirement.

The study is scientifically sound and meets the requirements for an avian single dose oral LD50 test.

D. Adequacy of the Study:

- (1) Classification: Core.
- (2) Rationale: N/A
- (3) Repairability: N/A

15. **COMPLETION OF ONE-LINER:** Yes; August 2, 1989.

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TABLE 2

AVERAGE BODY WEIGHT AND ESTIMATED FEED CONSUMPTION OF BOBWHITE

GAVAGED WITH VERBENONE

Dosage mg/kg	Average Body Weight in Grams								Estimated Feed Consumption Grams/Bird/Day		
	Day 0	Change	Day 3	Change	Day 7	Change	Day 14	Total Change	Days 0-3	Days 4-7	Days 8-14
Control											
Males	203	6	209	3	212	3	215	12	28	28	25
Females	191	4	195	3	198	2	200	9	29	33	22
39											
Males	194	6	200	1	201	2	203	9	26	35	25
Females	189	6	195	4	199	4	203	14	29	37	25
65											
Males	198	7	205	1	206	-3	203	5	27	33	25
Females	195	6	201	4	205	2	207	12	25	29	21
108											
Males	194	8	202	1	203	3	206	12	28	31	22
Females	199	5	204	3	207	-17	190	-9	39	42	29
180											
Males	201	3	204	3	207	2	205	8	31	34	27
Females	197	3	200	3	203	4	207	10	19	31	27
300											
Males	199	6	205	3	208	1	209	10	31	33	25
Females	190	7	197	2	199	3	202	12	27	28	23

Accession		Chemical Name	Chemical Class	Page	of	Reviewer/Date	Value/Std
messey No: 128486		Verbenone		1	1		
Study/Species/Lab/		Results					
14-Day Single Dose Oral LD50		LD50 > 300 mg/kg * (95% C.L.)		Contr. Mort. (X) = 0			
Species		Slope = N/A		# Animals/Level = 10		Age (Days) =	
Colinus virginianus						Sex = SM/SF	
Lab		14-Day Dose Level mg/kg/(X Mortality)		M. WHITTEN CORE			
Wildlife International Ltd.		39 (0), 65 (0), 108 (0), 180 (0), 300 (0)		8/2/89			
Acc. 405399-03		Comments: * BASED ON NOMINAL DOSAGES					
14-Day Single Dose Oral LD50		LD50 = mg/kg. (95% C.L.)		Contr. Mort. (X) =			
Species		Slope =		# Animals/Level =		Age (Days) =	
						Sex =	
Lab		14-Day Dose Level mg/kg/(X Mortality)					
		(, , , , ,)					
Acc.		Comments:					
8-Day Dietary LC50		LC50 = ppm (95% C.L.)		Contr. Mort. (X) =			
Species		Slope =		# Animals/Level =		Age (Days) =	
						Sex =	
Lab		8-Day Dose Level ppm/(X Mortality)					
		(, , , , ,)					
Acc.		Comments:					
8-Day Dietary LC50		LC50 = ppm (95% C.L.)		Contr. Mort. (X) =			
Species		Slope =		# Animals/Level =		Age (Days) =	
						Sex =	
Lab		8-Day Dose Level ppm/(X Mortality)					
		(, , , , ,)					
Acc.		Comments:					
48-Hour LC50		LC50 = pp (95% C.L.)		Contr. Mort. (X) =			
Species		Slope =		# Animals/Level =		Sol. Contr. Mort. (X) =	
						Temperature =	
Lab		48-Hour Dose Level pp/(X Mortality)					
		(, , , , ,)					
Acc.		Comments:					
96-Hour LC50		LC50 = pp (95% C.L.)		Con. Mort. (X) =			
Species		Slope =		# Animals/Level =		Sol. Con. Mort. (X) =	
						Temp. =	
Lab		96-Hour Dose Level pp/(X Mortality)					
		(, , , , ,)					
Acc.		Comments:					
96-Hour LC50		LC50 = pp (95% C.L.)		Con. Mort. (X) =			
Species		Slope =		# Animals/Level =		Sol. Con. Mort. (X) =	
						Temp. =	
Lab		96-Hour Dose Level pp/(X Mortality)					
		(, , , , ,)					
Acc.		Comments:					